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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William R. Freeman

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7590

09/16/2010

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1617

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,546	<b>Applicant(s)</b> FREEMAN, WILLIAM R.	
	<b>Examiner</b> GIGI HUANG	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-12,14,16-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 19-23,25-37 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,14,16-18,24,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The response filed June 30, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - a. Claims 1, 14, 24 have been amended.
  - b. Claim 2-3, 15 has been cancelled.
2. Claims 1, 4-12, 14, 16-37, 40-42 are pending in the case.
3. Claims 1, 4-12, 14, 16-18, 24, 41-42 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.

### ***New Grounds of Rejection***

Due to the amendment of the claims the new grounds of rejection are applied:

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4-12, 14, 16-18, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strong et al. (U.S. Pat. Publication 2003/0087889) in view of

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Freeman et al. (Simultaneous Indocyanine Green and Fluorescein Angiography Using a Confocal Scanning Laser Ophthalmoscope).

Strong et al. teaches a method of selection and treatment of patients with occult choroidal neovascular lesions (CNV) including patients with age-related macular degeneration (AMD) with photodynamic therapy (Abstract). Strong et al. teaches that laser photocoagulation is limited to well-demarcated extrafoveal and juxtafoveal CNV and small well-demarcated subfoveal lesions unlike photodynamic therapy (PDT) with verteporfin which can selectively destroy the CNV without significant destruction of the overlying tissue and possibly occluding new vessels with the CNV lesion. Strong teaches assessment of the lesion (e.g. Example 1-2) with a fluorescein angiogram, determination if the lesion spares the foveal center ("not subfoveal", i.e. extrafoveal, juxtafoveal) or in the avascular zone as CNV can occur anywhere in the fundus ([147], Example 2), selecting the treatment, and providing PDT by administering the photosensitizer (verteporfin), allowing time for the photosensitizer to localize in the lesion, followed by light application at a wavelength of 689nm (verteporfin absorption spectrum, [8]), and follow up angiography is preferred at least every 3 months with repeated PDT if new leakage is present. The light sources commonly used for these light wavelengths (e.g. 689nm) are non-thermal lasers (coherent light) and LEDs (light emitting diodes, non-coherent light- paragraph 8).

The lesion size and location are determined prior to treatment with baseline measurements that can be determined by fluorescein angiographic photographs and a fundus camera (e.g. Example 2- [131-152]). The photodynamic therapy can be

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performed with a number of photoactive compounds including hematoporphyrins, texapyrins, and verteporfin (also known as BPD-MA, absorption spectrum 689nm as addressed above) where the absorption spectrum of the compound is typically between 350nm to 12nm, more preferred 400-900nm, and even more preferred 600-900nm (e.g. [44-49]); were mixture of these compounds can be used for the method depending on the absorption of light preferred. The compounds can be delivered in various forms (e.g. liposomal) and administered in several ways including intravenously, orally, and locally [86-90]. The fluence for irradiation of the area can vary widely depending on the depth of tissue, type of tissue, fluid in the area, but the preferred range is from about 20-200J/cm<sup>2</sup> (paragraph 101), with particular fluences of 50, 75, and 100 J/ cm<sup>2</sup> taught, and 50J/ cm<sup>2</sup> exemplified with verteporfin (Example 3 [159-161], claimed) and evaluation with fluorescein angiography (paragraph 162) (see full document, specifically Abstract, [3-4, 7-8, 10-12, 14-24, 27-28, 40, 44-85, 85-96, 101-113, 131-152, 159-162], claims).

Strong et al. does not expressly teach the use of a high speed scanning laser ophthalmoscope (SLO) and indocyanine green as a photoimaging agent, but does teach the use of a fundus camera and angiography with fluorescein (e.g. [142-147] ).

Freeman et al. teaches that a compact digital confocal scanning laser ophthalmoscope (high speed SLO) with true simultaneous fluorescein and indocyanine green (ICG) angiography. Freeman teaches that while fluorescein and ICG angiography are both useful in the diagnosis and treatment of many retinal diseases, sometime both tests must be used and utilizing both can be time-consuming and use multiple injections, where their method with the SLO/fluorescein/ICG overcomes these issues

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and has the advantage of simultaneous angiography with optimal visualization of retinal and subretinal structures in fluorescent digital (near-real time) imaging plus increased convenience and speed (took less time and less injections).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the compact scanning laser ophthalmoscope (SLO) with fluorescein/ICG instead of fundus camera photography and traditional fluorescein angiography, as suggested by Freeman, and produce the instant invention as it is obvious to substitute the photographic imaging/angiograph of the traditional fundus camera and fluorescein angiography, with the (SLO) with fluorescein/ICG as it has substantial advantages such as better quality, greater image detail, and greater convenience (faster, less injections) which are desirable advantages where one would be motivated to substitute this form of imaging over the other.

8. Claims 1, 4-8, 10-12,14, 16-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy with Verteporfin) and Roach (EyeNet Magazine March 2001).

Levy et al. teaches a method of photodynamic therapy for unwanted neovasculture in the eye specifically in Age-related macular degeneration. Fundus photography, histological examination, and fluorescein angiography were used to observe and identify the choroidal neovascularization (CNV). BPD-MA porphyrin (verteporfin), was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of CNV. The

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fluence for treatment in the examples was 50, 75, 100 or 150 joules/cm<sup>2</sup>. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.1, lines 18-48, 55-63, Col. 2, lines 13-32, 39-52, Col. 3, lines 32-40, 45-68, Col. 4, lines 1-64, Col. 6, lines 1-36, Col. 8, lines 26-45, Examples 1-2, Col. 9-10, Example 3 and 4, Col. 11 Table 5). Levy also teaches that laser photocoagulation treatment is also available for the condition and depending on the side effects, scarring, and level of prognosis; strategies such as photodynamic therapy are desirable since there is greater selective closure of the blood vessels.

Levy et al. does not expressly teach the method for treating an aberrant choroidal neovascularization in an extrafoveal area of the eye or use of high speed scanning laser ophthalmoscope.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patients with subfoveal choroidal neovascularization (CNV) which is a found in AMD patients and should be considered for the therapy of CNV that is not subfoveal in certain situations such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result. Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a

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juxtafoveal or extrafoveal membrane with PDT first and see the results. If the lesion continues to grow, then thermal lasers (e.g. laser photocoagulation) could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you cannot. Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG or ICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize PDT for CNV in the extrafoveal area of the eye, as suggested by Jampol, to utilize the SLO with ICG, as suggested by Roach, and produce the instant invention as it is obvious to utilize the PDT in the extrafoveal region, as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal and could allow the survival of the retina over the CNV which is desirable. It also obvious to utilize the SLO with high-speed ICG, as the imaging technique would also be invaluable in photodynamic therapy to allow the physician to produce real time imaging where the dye used can be seen moving through



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the choroidal vessels and identify the aberrant vessels and improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because as taught by Jampol and Roach, there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV. Additionally, as the SLO coupled with the HSICG operates in real time, it is possible to immediately treat an area as it is identified. The system increases the number of vessels you can see, thereby allowing the practitioner to increase number of vessels to be treated which results in increasingly effective and accurate treatment which is desirable.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims above, and in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Levy et al. in view of Jampol et al. and Roach are discussed above. Levy et al. in view of Jampol et al. and Roach does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143), which is fully incorporated by reference in Levy et al. (U.S. Pat. No. 5798349), teaches that the photosensitizing compounds can

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be administered for systemic or topical use in formulations well known in the art (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have been obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins, as topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims above, and in view of LumaCare (Press release - <http://lumacare.com/EMEA/pr3.html>).

The teachings of in view of Jampol and Roach are discussed above. Levy also teaches the use of coherent light (lasers) in photodynamic therapy. Levy in view of Jampol and Roach does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective. This is desirable as not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income.

11. Claims 1, 4-8, 10-12, 14, 16-17, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001).

Sullivan teaches the method of treating choroidal neovascularization (CNV) caused by age-related macular degeneration. The method utilized fluorescein angiograms to determine the presence, location, and extent of the CNV by injection of a dye into a vein and multiple photographs of the retina. Treatment followed with the use of photodynamic therapy (PDT) utilizing verteporfin coupled with low-density lipoprotein and injected intravenously. A non-thermal laser light was then used to activate the verteporfin at the area of neovascularization. The wavelength used was 689 nm,

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corresponding to the absorption peak of the verteporfin dye. The result was thrombosis and occlusion of the abnormal vessel (Pages 396-398).

Sullivan et al. does not expressly teach the method for treating an aberrant choroidal neovasculation in an extrafoveal area of the eye or the use of a high speed scanning laser ophthalmoscope.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patients with subfoveal choroidal neovascularization (CNV) which is a found in AMD patients and should be considered for the therapy of CNV that is not subfoveal in certain situations such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result. Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a juxtafoveal or extrafoveal membrane with PDT first and see the results. If the lesion continues to grow, then thermal lasers (e.g. laser photocoagulation) could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be

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better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you cannot. Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG or ICG) coupled with a scanning laser ophthalmoscope (SLO) that can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize photodynamic therapy for CNV in the extrafoveal area of the eye, as suggested by Jampol et al., to utilize SLO with HSICG, as suggested by Roach, and produce the instant invention as it is obvious to utilize the PDT in the extrafoveal region as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal and could allow the survival of the retina over the CNV which is desirable. It also would have been obvious to one of skill in the art at the time the claimed invention was made to utilize the SLO with HSICG, as the imaging technique would also be invaluable in PDT to allow the physician to produce real time imaging where the dye used can be seen moving through the choroidal vessels and identify the aberrant vessels and improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively. This is desirable as addressed by Jampol and Roach, there are some situations where

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the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV. Additionally, as the SLO coupled with the HSICG operates in real time, it is possible to immediately treat an area as it is identified. The system increases the number of vessels you can see, thereby allowing the practitioner to increase number of vessels to be treated which results in increasingly effective and accurate treatment which is desirable.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims above, and further in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Sullivan, Jampol et al., and Roach are discussed above. Sullivan in view of Jampol et al. and Roach does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143) teaches that the photosensitizing compounds can be administered in formulations well known in the art for systemic or topical use (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention as it is obvious to try topical administration as it would be

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another method of administration if adequate intravenous lines would not be available such as collapsed veins and it is desirable as topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims above, and in view of LumaCare (<http://lumacare.com/EMEA/pr3.html>).

The teachings of Sullivan, Jampol et al., and Roach are discussed above. Sullivan, Jampol et al., and Roach teach the use of coherent light (lasers) in photodynamic therapy but does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for

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various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective. This is desirable because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income.

14. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims above, and further in view of Miller et al. (U.S. Pat. No. 5707986).

The teachings of Levy et al. in view of Jampol et al. and Roach are discussed above. Levy et al. in view of Jampol et al. and Roach does not expressly teach the fluence of the photoactivating light.

Miller et al. teaches the use of a green porphyrin, BPD-MA (verteporfin) for treating the choroidal neovascularization and other conditions. The BPD-MA was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization (CNV). Miller teaches that the porphyrin is used within the range of about 0.1 to about 20mg/kg, preferably from about 0.15-2.0mg/kg. Specifically, when the green porphyrin dose is reduced from about 2 to about 1mg/kg, there is a corresponding increase in the fluence required to close the choroidal neovascular tissue, such as from about 50 J/cm<sup>2</sup> to about 100J/cm<sup>2</sup>. The green porphyrin has a maximum absorbance of about 550 to



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695nm which is the wavelength used to radiate the porphyrin. The fluence for treatment can vary depending the tissue, depth, and amount of fluid/blood, but preferably varies from about 50-200 J/cm<sup>2</sup>. The examples utilized verteporfin at a wavelength of 692, and fluences of 50, 100, and 150 joules/cm<sup>2</sup> to effectively close the CNV. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.3, lines 1-68, Col. 4, lines 1-33, Col. 5, lines 29-55, Col. 7, lines 17-65, Col. 8, lines 55-68, Col.10-12, Example 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the fluence levels for photodynamic therapy as suggested by Jampol et al., with as suggested by Miller, and produce the instant invention. It would have been obvious to one of skill in the art to use the taught fluence amounts of photoactive light for irradiation of verteporfin effective to close the choroidal neovascularization. It is obvious to use the amounts and ranges taught by Miller for the fluence as the dye (verteporfin) utilized is the same, with photoactive light in the same wavelength ranges taught, and for the same purpose for the same conditions to yield the same result, the closure of the abnormal vasculature. It is desirable to use known amounts and technique for the same treatment with the taught amounts and ranges known to be effective for closure of the choroidal neovascularization.

### ***Response to Arguments***

15. Claims 1-2, 4-8, 10-11, 13-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. and Roach.

Claim 2 and 15 is cancelled, the rejection is moot.

Applicant's arguments filed 6/30/2010 have been fully considered but they are not persuasive. Applicant's argument centers on the assertion that as the claims are to a subject with AMD, that Jampol is not prior art. This is not persuasive as applicant's argument is against the reference individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. It is noted for Applicant as a courtesy that Levy addresses that CNV is present in AMD and Jampol addresses the presence of CNV in AMD where Jampol is relevant ophthalmic art to CNV which is a known element of AMD. Accordingly, the rejection is maintained.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. and Roach as applied to claims above, and in view of Levy et al. (U.S. Pat. No. 4920143).

Applicant's arguments filed 6/30/2010 are directed to Levy in view of Jampol and Roach which is addressed above. Accordingly, the rejection is maintained.

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. and Roach, and in view of LumaCare.

Applicant's arguments filed 6/30/2010 are directed to Levy in view of Jampol and Roach which is addressed above. Accordingly, the rejection is maintained.

18. Claims 1-2, 4-8, 10-11, 13-17, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Jampol et al. and Roach.

Claim 2 and 15 is cancelled, the rejection is moot.

Applicant's arguments filed 6/30/2010 have been fully considered but they are not persuasive. Applicant's argument centers on the assertion that as the claims are to a subject with AMD, that Jampol is not prior art. This is not persuasive as applicant's argument is against the reference individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. It is noted for Applicant as a courtesy that Sullivan addresses that CNV is caused by AMD and Jampol addresses the presence of CNV in AMD where Jampol is relevant ophthalmic art to CNV which is a known element of AMD. Accordingly, the rejection is maintained.

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Jampol et al. and Roach, and further in view of Levy et al. (U.S. Pat. No. 4920143).

Applicant's arguments filed 6/30/2010 are directed to Sullivan in view of Jampol and Roach which is addressed above. Accordingly, the rejection is maintained.

20. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Jampol et al. and Roach, and in view of LumaCare.

Applicant's arguments filed 6/30/2010 are directed to Sullivan in view of Jampol and Roach which is addressed above. Accordingly, the rejection is maintained.

21. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Jampol et al. and Roach , and further in view of Miller et al.

Applicant's arguments filed 6/30/2010 are directed to Sullivan in view of Jampol and Roach which is addressed above. Accordingly, the rejection is maintained.

***Conclusion***

22. Claims 1, 4-12, 14, 16-18, 24, 41-42 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FEREDOUN SAJJADI can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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